DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Shenzhen Gsd Tech. Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K142186
Trade/Device Name: Diode Laser Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 29, 2014
Received: August 14, 2014

Dear Diana Hong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142186

Device Name
Diode Laser Hair Removal System

Product Model: GP900A/ GP900Q

Indications for Use *(Describe)*

The Diode Laser Hair Removal System is intended for use in dermatologic and general surgical procedures.
The Fast Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth.
The Free Setting Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth.
The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit #3 510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K142186

1. Date of Submission: July 29, 2014

2. Sponsor Identification

Shenzhen GSD Tech Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Diode Laser Hair Removal System
Proposed Device Common Name: Laser Hair Removal instrument
Product Model: GP900A/ GP900Q

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument;
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General& Plastic Surgery;

Intended Use Statement:

The Diode Laser Hair Removal System is intended for use in dermatologic and general surgical procedures.
The Fast Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth.
The Free Setting Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth.
The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

5. Predicate Device Identification

510(k) Number: K123483
Product Name: Diode Laser
Manufacturer: Beijing Syntech Laser Co., Ltd

6. Device Description

The diode laser hair removal system is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a semiconductor diode with invisible infrared radiation as a laser source (808 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a footswitch.

The proposed diode laser removal system has two models, GP900A and GP900Q. Both GP900A and GP900Q have the same functions modules, such as the power supply system, central control system, cooling system, laser delivery system and safety feature, and same working mode, such as Fast mode and Free setting mode.

The GP900A is a standard case with wheels to allow easy movement on the floor. The GP900Q is a desktop case.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1-2005+CORR.1:2006+CORR.2:2007, Medical Electrical Equipment- Part 1: General requirements for safety.
IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

IEC 60601-2-22:2007+A1:2012, Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity.
ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, energy source and fluency, etc.

Table 3-1 Comparison of Technology Characteristics between GP900A and Predicate Device

Item	Proposed Device(s)		Predicate Device K123483	
Product model	GP900A		DLH-06	
Product Code	GEX		GEX	
Regulation Number	21 CFR 878.4810		21 CFR 878.4810	
Intended Use	The Diode Laser Hair Removal System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth. The Free Setting Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth. The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.		The Diode Laser is intended for use in dermatologic and general surgical procedures. The Standard Mode is intended for hair removal, permanent hair reduction. The FHR Mode is intended for hair removal, permanent hair reduction. The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.	
Configuration	Laser system and handpiece		Laser system and handpiece	
Energy Source	Diode laser		Diode laser	
Wavelength	808 nm		808 nm	
Spot size	1.44cm^2		1.2cm^2	
Working Mode	Fast Mode	Free Setting Mode	FHR Mode	Standard Mode
Power	144W	518.4W	120W	432W
Power density	100W/ cm^2	360W/ cm^2	100W/ cm^2	360W/ cm^2
Fluency (energy density)	⩽ 10 J/cm^2	⩽ 120 J/cm^2	⩽ 10 J/cm^2	⩽ 120 J/cm^2
Repetition Rate	⩽10 Hz	⩽3 Hz	⩽10 Hz	⩽3 Hz
Pulse Duration	⩽ 20 ms	5-200 ms	⩽ 20 ms	5-200 ms
Product Appearance Design	Standard case		Desktop case	
Electrical Safety	IEC 60601-1, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1		IEC 60601-1, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1	
Biocompatibility	ISO 10993-5 and ISO 10993-10		ISO 10993-5 and ISO 10993-10	
Performance	IEC 60601-1, IEC 60601-2-22 and IEC 60825-1		IEC 60601-1, IEC 60601-2-22 and IEC 60825-1	

Table 3-2 Comparison of Technology Characteristics between GP900Q and Predicate Device

Item	Proposed Device(s)		Predicate Device K123483	
Product model	GP900Q		DLH-06	
Product Code	GEX		GEX	
Regulation Number	21 CFR 878.4810		21 CFR 878.4810	
Intended Use	The Diode Laser Hair Removal System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth. The Free Setting Mode is intended for hair removal of unwanted hair, and permanent reduction in hair regrowth. The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.		The Diode Laser is intended for use in dermatologic and general surgical procedures. The Standard Mode is intended for hair removal, permanent hair reduction. The FHR Mode is intended for hair removal, permanent hair reduction. The Diode Laser Hair Removal System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.	
Configuration	Laser system and handpiece		Laser system and handpiece	
Energy Source	Diode laser		Diode laser	
Wavelength	808 nm		808 nm	
Spot size	1.44cm^2		1.2cm^2	
Working Mode	Fast Mode	Free Setting Mode	FHR Mode	Standard Mode
Power	120W	432W	120W	432W
Power density	100W/ cm^2	360W/ cm^2	100W/ cm^2	360W/ cm^2
Fluency (energy density)	⩽ 10 J/cm^2	⩽ 120 J/cm^2	⩽ 10 J/cm^2	⩽ 120 J/cm^2
Repetition Rate	⩽10 Hz	⩽3 Hz	⩽10 Hz	⩽3 Hz
Pulse Duration	⩽ 20 ms	5-200 ms	⩽ 20 ms	5-200 ms
Product Appearance Design	Standard case		Desktop case	
Electrical Safety	IEC 60601-1, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1		IEC 60601-1, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1	
Biocompatibility	ISO 10993-5 and ISO 10993-10		ISO 10993-5 and ISO 10993-10	
Performance	IEC 60601-1, IEC 60601-2-22 and IEC 60825-1		IEC 60601-1, IEC 60601-2-22 and IEC 60825-1	

The proposed device, Diode Laser Hair Removal System, is determined to be Substantially Equivalent (SE) to the predicate device, Diode Laser, in respect of safety and effectiveness.